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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,449	09/26/2006	Takashi Okuda	060734	1239

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EXAMINER	
KINSEY WHITE, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,449	OKUDA ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1, 2, 3, 4, 6 and 7 are objected to because of the following informalities:

Claims 1, 2, 3, and 6 recite "A recombinant herpesvirus (excluding infectious laryngotracheitis virus) having a DNA . . . ." Applicants should amend the claims to recite "wherein the recombinant herpesvirus is not infectious laryngotracheitis virus." Applicants are reminded that dependent claims contain the limitations of the independent claim from which they depend; therefore, is it not necessary to repeat the exclusionary language in dependent claims 2, 3, and 6. Appropriate correction is required.

Claim 2 should recite "in which the DNA encoding." Claim 4 should recite "wherein the herpesvirus that infects avians." Claim 7 should recite "wherein the herpesvirus that infects avians."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to, *inter alia*, a recombinant herpesvirus (excluding infectious laryngotracheitis virus) having a DNA that encodes a polypeptide comprising 429 amino acids at the amino terminal end of a protein encoded by the gB gene of infectious laryngotracheitis virus or a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide. For this rejection, it is assumed that applicants intend the phrase "a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide" to refer to SEQ ID NO:4 as the polypeptide.

The written description rejection is made because the claims are interpreted as being drawn to a genus of recombinant viruses having a DNA that encodes a polypeptide (e.g., SEQ ID NO:4) in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide. The applicable standard for the written description requirement can be found in MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609; Vas- Cath Inc. v. Mahurkar, 19 USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004). To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional

characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is SEQ ID NO:4. There is no disclosure of any particular portion of the structure that must be conserved or deleted, added, or substituted.

The specification discloses at page 5 that "[o]ne or a plurality of amino acids of the amino acid sequence set forth in SEQ ID NO: 4 may be deleted, added or substituted." However, the specification does not indicate which portions of SEQ ID NO:4 are essential or which portions of SEQ ID NO:4 can be modified.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

The court clearly states in Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented what is claimed. As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides with one or a plurality of amino acids of SEQ ID NO: 4 which can be deleted, added or substituted. Given that the specification has only described the structure of SEQ ID NO:4, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a DNA that encodes . . . a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide." It is not clear if applicants mean any polypeptide where a plurality of amino acids have been deleted, added, or substituted or SEQ ID NO:4 where a plurality of amino acids have been deleted, added, or substituted. The metes and bounds of the claimed product cannot be determined without further clarification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Keeler et al (U.S. Patent No. 5,443,831).

The claims are drawn to a recombinant herpesvirus (excluding infectious laryngotracheitis virus) having a DNA that encodes a polypeptide comprising 429 amino

acids at the amino terminal end of a protein encoded by the gB gene of infectious laryngotracheitis virus or a polypeptide in which one or a plurality of amino acids have been deleted, added, or substituted in said polypeptide.

Keeler et al. discloses a recombinant vaccine comprising the ILTV gB protein inserted in non-essential sequences of a viral vector. The preferred viral vectors include Marek's Disease Virus and Herpes Virus of Turkeys, which infect avians (see col. 6, line 30 to col. 7, line 26).

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Audonnet et al (U.S. Patent No. 5,980,906).

Audonnet et al. discloses a vaccine comprising antigens (e.g., the ILTV gB protein) inserted into an avian herpes virus selected from Marek's disease viruses, in particular HVT, the infectious laryngotracheitis virus ILTV and herpes of ducks. The Marek's disease viruses, and more especially the HVT virus, are preferred viral vector (see col. 2, lines 44 to col. 3, line 32).

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cochran et al (U.S. Patent No. 6,183,753).

Cochran et al. discloses a vaccine comprising antigens (e.g., the ILTV gB protein) inserted into a chimera comprising HVT and MDV (see col. 5, line 66 to col. 6, line 13) or into a recombinant HVT. The antigen can be the gB of ILTV (see col. 9, lines 10-15 and 29-33).

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cochran et al (WO 93/25665).

Cochran et al. discloses a vaccine comprising antigens (e.g., the ILTV gB protein) inserted into HVT or MDV (see, for example, page 19, lines 8-13).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13 and 24 of U.S. Patent No. 6,632,664 (the '664 patent) in view of Tong et al. (Avian Pathology, 2001, 30:142-148). Although the conflicting claims are not identical, they are not patentably distinct from

each other because both sets of claims are drawn to a recombinant herpesvirus comprising a foreign gene encoding a polypeptide from ILTV.

The '664 patent does not specifically teach the use of the gB gene from ILTV as the foreign gene; however, it would have been obvious to one of ordinary skill in the art to use the gB gene of ILTV in the herpesvirus recombinants of the '664 claims based on the teachings of Tong et al. Tong et al. teaches that the gB protein of ILTV is a prime candidate for avian vaccines and that a subunit vaccine made of a 205kDa complex containing the gB of ILT protected 100% of chickens against clinical disease and viral replication (see page 144). There would have been a reasonable expectation of success given the fact that Tong et al. used the gB of ILTV in a recombinant background to protect 100% of immunized chickens.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E. Kinsey, Ph.D.
Examiner
Art Unit 1648

/nk/

/Stacy B. Chen/ 10-25-2007
Primary Examiner, TC1600